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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,468	06/14/2006	Myriam Richelle	3712036.00737	6965

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EXAMINER	
CHEN, CATHERYNE	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
10/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/596,468	RICHELLE ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-14,16,19,20 and 27* is/are pending in the application.

4a) Of the above claim(s) *1-8,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 11-14, 16 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments filed on Aug. 6, 2010 has been received and entered.

Claims 9, 11-14, 16, and 27 have been examined on the merits (claims 1-8, 19, and 20 remain withdrawn from consideration).

Response to Arguments

Applicant's arguments with respect to claims 9, 11-14, 16, and 27 have been considered but are moot in view of the new ground(s) of rejection set forth below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11-14, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bidel (US 5849786) as evidenced by Global Herbal Supplies (http://www.globalherbalsupplies.com/herpes/symptoms.htm).

Bidel teaches hesperidin orally absorbed by a man subject at first sign of herpes outbreak (Example 2) to reduce the effects of very significant infectiousness during

second phase of herpetic cluster burst out (column 2, lines 66-67; column 3, lines 1-2). Herepes simplex virus attack the skin (column 1, lines 15-17). A method for treating herpes administered to a patient in need thereof (Claim1), administered orally (Claim 2). Global Herbal Supplies teaches painful inflamed blisters develop around infected area (page 2, line 1). Thus, inflammation of the skin is taught. Ageing is an inherent part of life; thus, administering the compound would result in reducing ageing on skin. Hesperidin can be extracted from citrus fruits and the limitation in Claim 11 is not given patentable weight to the claims.

Claims 9, 11-14, 16, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Warren et al. (US 5587176) and as evidenced by Hesperidin170 (http://170.107.206.70/drug_info/nmdrugprofiles/nutsupdrugs/hes_0295.shtml).

Warren et al. teaches treatment of acne in mammalian skin and scalp (column 1, lines 10-11) through control of sebaceous gland activity to reduce oil in skin and hair (column 1, lines 18-21). A method of treating acne comprising safe and effective amount of hesperetin, involving treatment of mammalian skin and scalp due to increased sebum production (column 2, lines 3-6, 17-21). An anti-inflammatory agent may include hesperetin active agent for treatment of acne (column 8, lines 65-66). Oral dosage form of hesperetin is administered at from about 0.1 mg/kg of body weight to about 500 mg/kg (column 12, lines 55-60). Two capsules, each containing 50 mg, is administered to a 60 kg human in need of treatment for existing acne (Example II). Hesperetin is the aglycone equivalent of hesperidin (see Description, paragraph 3,

Hesperidin170). The treatment would inherently affect hair gloss because the ingredient affecting sebum gland's oil product would affect hair shine. Ageing is an inherent part of life; thus, administering the compound would result in reducing ageing on skin. Hesperidin can be extracted from citrus fruits and the limitation in Claim 11 is not given patentable weight to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 11-14, 16, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warren et al. (US 5587176) and as evidenced by Hesperidin170 (http://170.107.206.70/drug_info/nmdrugprofiles/nutsupdrugs/hes_0295.shtml).

Warren et al. teaches treatment of acne in mammalian skin and scalp (column 1, lines 10-11) through control of sebaceous gland activity to reduce oil in skin and hair (column 1, lines 18-21). A method of treating acne comprising safe and effective amount of hesperetin, involving treatment of mammalian skin and scalp due to increased sebum production (column 2, lines 3-6, 17-21). An anti-inflammatory agent may include hesperetin active agent for treatment of acne (column 8, lines 65-66). Oral dosage form of hesperetin is administered at from about 0.1 mg/kg of body weight to about 500 mg/kg (column 12, lines 55-60). Two capsules, each containing 50 mg, is administered to a 60 kg human in need of treatment for existing acne (Example II). Hesperetin is the aglycone equivalent of hesperidin (see Description, paragraph 3, Hesperidin170). The treatment would affect hair gloss because the ingredient affecting sebum gland's oil product would affect hair shine. Ageing is a part of life; thus, administering the compound would result in reducing ageing on skin. Hesperidin can be extracted from citrus fruits and the limitation in Claim 11 is not given patentable weight to the claims.

However, Warren et al. does not teach the amount from 0.01 to 1 g of aglycone equivalent of flavanone compound.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising from 0.01 mg to 1 g of hesperetin for the following reasons. The references do teach the composition for treating skin and scalp. Warren et al. teaches dosage form of hesperetin is administered at from about 0.1 mg/kg of body weight to about 500 mg/kg (column 12,

lines 55-60). Thus, it would have been obvious to make a concentrated composition containing hesperetin for use as a pharmaceutical agent. Additionally, the amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, especially within the ranges taught by the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Christopher R. Tate/
Primary Examiner, Art Unit 1655